Unanticipated human toxicology of recombinant proteins.

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Recombinant human proteins play already an important role in therapy, e.g. erythropoietin and colony stimulating factors, while several promising candidates such IL-6, IL-12, thrombopoietin and others are in clinical development. Since the recombinant proteins are copies of endogenous proteins, it was assumed that they would be well tolerated. While this assumption is correct for some, other proteins proved to be a highly toxic. Therefore, preclinical safety assessment of these proteins is necessary. Based on the experience with several proteins, some guidance for the safety assessment can be given. Furthermore, data are presented demonstrating that preclinical toxicity studies have a predictive value for man. Limitations of the classical approach of safety tests and new concepts are discussed.

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